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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,947	01/05/2004	Mitsutoshi Tatara	159-82	2059

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/750,947

Applicant(s)

TATARA ET AL.

Examiner

Blessing M. Fubara

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/17/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of formal drawings filed on 06/17/04 in response to Pre-Exam Formalities Notice, IDS and preliminary amendment filed 06/17/04 and 01/05/04 respectively. Claims 1-6 are pending.

Priority

Examiner acknowledges applicants' claim to benefit of prior application serial number 09/786,815 filed June 25, 2001, which is a 371 of PCT/JP00/04651 filed July 12, 2000.

Claim Objections

1. Claims 4-12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 1, the phrase "other additive" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "other additive"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

What is included or excluded from "other additive"?

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5. Claims 14 and 15 provides for the use of water insoluble polymer (claim 14) and use of a solvent (claims 15), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claims 14 and 15 are examined as a method of producing pharmaceutical composition and the method comprises mixing or dissolving the water insoluble polymer in a solvent

Claims 14 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-10 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al. (US 5,648,399).

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Friedman discloses a method of treating gingivitis, oral plaque and oral or dermatological fungal infection (abstract). Friedman's method comprises administering a composition that comprises methacrylic acid copolymer, a solvent and an active agent and the polymer of Friedman is selected from EUDRAGIT L, EUDRAGIT S, EUDRAGIT RS and EUDRAGIT RL (abstract; column 8, lines 6-15). The active agent is selected from antifungal agents, antibiotics, anti-viral agents, anti-inflammatory agents and growth factors (column 10, line 64 to column 11 line 5); and penicillins antibiotics are used in Friedman (column 13, lines 15-20). Friedman's composition further comprises plasticizer such as dibutyl phthalate, adhesive polymer, coloring agent in powder form (column 11, lines 16-25), citric acid, lysine, aspartic acid that are used to adjust the pH, lipids, oils and fats (column 11, lines 54-61).

The instant claims are directed to composition that contains water insoluble polymer, solvent and active agent. The polymer is defined in dependent claim 4 and active agents are defined dependent claim 2. "For topical administration" is an intended use of the composition and "capable of dissolving the water soluble polymer" is a property of the solvent and these phrases are not accorded patentable weight in the composition claim. To expedite the prosecution, the use claims 14 and 15 are examined as a method of producing pharmaceutical composition and the method comprises mixing or dissolving the water insoluble polymer in a solvent. Friedman dissolves the polymer in ethanol in Example 1 and this process meets the process of dissolving or mixing the polymer in a solvent as directed by instant claim 14 and 15.

Although future intended use is not accorded patentable weight in composition claims, it is noted that the composition of Friedman is administered topically. Friedman meets the limitations of the claims.

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8. Claims 1, 2, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganguly et al. (US 4,743,598).

Ganguly discloses compositions that contain penem antibiotics, solvent, polymer, oils fillers, binders, disintegrants, buffering agents and the composition is formulated as lotions, creams and ointments (abstract; column 1, line 16 to column 3, line 61; column 3, lines 29-31). Although future intended use is not accorded patentable weight in composition claims, it is noted that the composition of Ganguly is administered topically. Ganguly meets the limitations of the claims.

9. Claims 1-10 and 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Lerner et al. (US 6,197,331).

Lerner discloses sustained release composition that comprises EUDRAGIT polymer, adhesives, release adjusting agents, pH adjusters, plasticizers including triethyl citrate, dibutylphthalate, diethylphthalate, acetyltriethyl citrate, tributyl citrate, acetyltetrabutyl citrate, triacetin, polyethylene glycol and castor oil (column 9, lines 10 to column 12 line 5). Lerner's composition may further contain flavorants, sweeteners and colorants (column 12, lines 12 to column 13 line 61); and among the active agents are anti-inflammatory agents, anesthetics, antibiotics and antifungal agents (column 15, line 12 to column 16 line 63). Lerner formulates the composition by mixing the active agent, the polymer, solvent and excipients and this process meets the limitation claims 14 and 15. Although future intended use is not accorded patentable weight in composition claims, it is noted that the composition of Lerner is administered topically. Lerner meets the limitations of the claims.

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10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
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Tech. Center 1600

